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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,167	01/25/2006	Jan Bastiaan Bouwstra	0807620.00107	1083

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IP Patent Docketing  
K&L GATES LLP  
599 Lexington Avenue  
33rd Floor  
New York, NY 10022-6030

EXAMINER
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DESAI, ANAND U

ART UNIT	PAPER NUMBER
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1656

MAIL DATE	DELIVERY MODE
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12/10/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/540,167	<b>Applicant(s)</b> BOUWSTRA ET AL.	
	<b>Examiner</b> ANAND U. DESAI	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 12-19, 21 and 23-29 is/are pending in the application.
- 4a) Of the above claim(s) 28 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-19, 21 and 23-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

1. This office action is in response to the amendment filed on August 21, 2008. Claims 20 and 22 have been cancelled. New claims 23-29 have been added. Claims 12-19, 21, and 23-29 are currently pending.

2. Newly submitted claims 28 and 29 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims are drawn to a composition similar to claim 22, which was withdrawn previously because of a lack of unity.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 28 and 29 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Claims 12-19, 21, and 23-27 are under examination currently.

### **Withdrawal of Rejections**

4. The rejection of claims 12 and 14-18 under 35 U.S.C. 102(b) as being anticipated by Wandrey et al. (U.S. Patent 5,906,940) is withdrawn based on the amendment to incorporate the limitation of less than 5% of hydroxyproline residues.

5. The rejection of claims 12-18 under 35 U.S.C. 102(b) as being anticipated by WO 91/07485 (IDS 6/17/2005; document #3) is withdrawn based on the amendment to incorporate the limitation of less than 5% of hydroxyproline residues.

6. The rejection of claims 19-21 under 35 U.S.C. 103(a) as being unpatentable over WO 91/07485 in view of WO 01/34646 (IDS 6/17/2005; document #4) is withdrawn based on the

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amendment to incorporate the limitation of less than 5% of hydroxyproline residues and the remarks filed July 1, 2008.

## **Pending Rejections**

### ***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. The term "essentially" in claim 24 is a relative term which renders the claim indefinite. The phrase "free of hydroxyproline" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Suggest, "...the gelatine-like protein is free of hydroxyproline...".

### ***Claim Rejections - 35 USC § 112***

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 12-19, 21, and 23-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

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was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

12. The rejection was explained in the office action mailed January 2, 2008 and applies to the newly submitted claims as well.

Response to Remarks

13. Applicant's state the specification describes the invention as now claimed in amended claim 12 in sufficient detail that a person of ordinary skill in the art will clearly conclude that applicant was in possession of the claimed subject matter. Applicant's state features that "make a gelatin-like protein similar to a gelatin protein" are described at page 8, line 8 et seq. of applicant's specification. These features include the absence of non-preferred 3-dimensional globular domains (page 8, line 9-12). Applicant's state the structure of a gelatine-like protein to be employed in the invention which has a molecular weight of 65 kDa as compared with a protein of molecular weight 145 kDa will be shorter with fewer Gly-Xaa-Yaa triplets and fewer prolines and the like. Applicant's cite the disclosure on page 10, line 30 to page 11, line 23 to state that a gelatine-like protein structure is disclosed.

Applicant's arguments filed July 1, 2008 have been fully considered but they are not persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., absence of 3-dimensional globular domains) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The issue in

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this application is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan, and the guidance presented in the instant specification and the prior art of record. Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skill in the art is unnecessarily and improperly extensive and undue. Therefore, absent direction/guidance regarding whether the gelatine-like protein identified by formula can tolerate the modifications contemplated a non-functional gelatine-like protein polymer may result and one of skill in the art would not be able to practice the claimed invention commensurate in scope with the claims.

### ***Conclusion***

14. No claims are allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANAND U. DESAI whose telephone number is (571)272-0947.

The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

December 6, 2008

/ANAND U DESAI/

Primary Examiner, Art Unit 1656